

PATENT APPLICATION

FACILITATED BALLOON CATHETER EXCHANGE

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Status: Small Entity

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CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application is a non-provisional of U.S. Patent Application Serial
5 No. 60/528,263 (Attorney Docket No. 021770-000900US), filed December 8, 2003, the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention. The present invention relates generally to medical apparatus and methods. More particularly, the present invention relates to catheters having
10 guide wire tubes disposed within expandable structures for facilitating catheter exchange over a guide wire.

[0003] Percutaneous transluminal angioplasty procedures have become a therapy of choice for treating stenosed regions in the patient's vasculature, particularly the coronary vasculature. Recently, the use of such angioplasty procedures has often been combined with
15 stent placement and/or radiation treatment to inhibit restenosis and hyperplasia following angioplasty. When performing such multiple, sequential treatments, it is usually necessary to "exchange" catheters which are used to perform each of the procedures. That is, the initial angioplasty treatment will be performed using a balloon angioplasty catheter. After the angioplasty is completed, a second catheter carrying a stent or other vascular prosthesis must
20 then be introduced to the treatment site. Introduction of the second catheter involves first removing the balloon angioplasty catheter and then placing the second catheter in the treatment region. Optionally, a third catheter may then be exchanged for the second in order to perform radiation or other treatments in order to inhibit hyperplasia.

[0004] In performing such multiple, sequential treatments, most physicians prefer to leave a
25 "guidewire" in place to the treatment location. A guidewire is a small diameter, highly flexible wire that can be steered to the target location through the vasculature and which then acts as a guide path for introducing and positioning the balloon angioplasty and other interventional catheters.

[0005] In the early days, balloon angioplasty catheters were designed to be introduced into
30 the vasculature in an "over-the-wire" manner. That is, the catheters were designed to have

passages, commonly referred to as guidewire lumens, which extended the entire distance from the distal end of the catheter to the proximal end of the catheter. The catheter could then be loaded over a proximal end of a guidewire which was already in place in the patient and then advanced over the guidewire until a distal end of the catheter reached the target site.

5 While functional, the need to maintain control of the guidewire while the interventional catheter was being introduced meant that the guidewire had to have an excess length outside of the patient which was greater than the length of the catheter being introduced. If the length were any shorter, the treating physician would not be able to hold on to the guidewire as the catheter was being introduced. Although necessary for catheter introduction, the excess
10 guidewire length (optionally in the form of a detachable extension) was very difficult to manage during other parts of the treatment.

[0006] To overcome the difficulties associated with very long guidewires "rapid exchange" or "monorail" balloon angioplasty catheters were developed. A number of specific designs have been developed over the years, and the rapid exchange catheters generally have a
15 shortened guidewire lumen which extends from a distal tip of the catheter to an exit port located closer to the distal end of the catheter than to the proximal end. By reducing the length of the guidewire lumen, the need for a guidewire having excess length outside of the patient is also reduced.

[0007] The use of rapid exchange catheters has become wide spread, and they have proven
20 to be particularly valuable for use as stent delivery catheters. Stent delivery catheters are normally used after an initial angioplasty treatment. In such cases, the angioplasty catheter will be removed and exchanged for the stent delivery catheter. Use of an angioplasty catheter having a rapid exchange design facilitates removal of the angioplasty catheter over short guidewires. Similarly, use of the stent delivery catheter having a rapid exchange design
25 facilitates introduction of the catheter over the guidewire which remains in place in the patient.

[0008] Most rapid exchange balloon angioplasty catheters have one of two basic designs. The first design was disclosed initially in U.S. Patent No. 4,762,100 to Bonzel. In the Bonzel design, an angioplasty balloon catheter having a balloon at the distal end of the shaft is
30 provided with a second guidewire tube positioned through the balloon in parallel with the distal tip of the shaft. While functional, this design adds to both the diameter and stiffness of the distal tip of the shaft, both of which properties make it more difficult to introduce the

catheter to narrow regions of the coronary and other vasculature. The second general design was first disclosed in U.S. Patent No. 5,048,548 to Yock et al. In the Yock design, the shaft of an angioplasty catheter is provided with at least two lumens, a balloon inflation lumen and a distal guidewire lumen. Usually, the two lumens are disposed in parallel over at least a portion of the length of the catheter body, again increasing the diameter and potential of the stiffness of the catheter. Moreover, the provision of a "notch" or hole in the side of the catheter body can cause the body to kink when delivered under certain conditions.

[0009] For these reasons, it would be desirable to provide improved and alternative apparatus, methods, kits, and the like for permitting the exchange of catheters over guidewires in a "rapid exchange" or other facilitated manner. It would be particularly desirable to provide improved balloon angioplasty and other catheters which can be introduced over a shortened guidewire without the need to provide a guidewire lumen anywhere in the catheter body and/or to provide a separate guidewire tube in parallel with or overlapping with the catheter body. Such designs should be compatible with catheters having very low profile distal ends, i.e., diameters of 5 Fr, 4 Fr, and even below, at their distal ends. At least some of these objectives will be met by the invention described and claimed hereinafter.

[0010] 2. Description of Background Art. Rapid exchange catheters having guidewire exchange devices are described in U.S. Pat. Nos. 5,281,203; 5,571,094; and 5,919,175.

Sleeves for positioning stents, drug infusion tubes, imaging transducers, and other interventional devices over balloon angioplasty catheters are described in U.S. Pat. Nos. 5,776,191; 5,810,869; and PCT Publication W097/07756. Rapid exchange and related catheters are described in U.S. Pat. Nos. 6,605,057; 6,533,754; 6,527,789; 6,569,180; 6,585,657; 6,478,807; 6,361,529; 6,277,093; 6,273,879; 6,248,092; 6,165,197; 6,129,708; 6,036,715; 6,056,722; 6,027,475; 6,007,517; 5,980,486; 5,980,484; 5,947,927; 5,921,971; 5,935,114; 5,919,164; 5,891,056; 5,855,685; 5,846,246; 5,833,659; 5,830,227; 5,827,241; 5,807,355; 5,814,061; 5,769,868; 5,749,888; 5,738,667; 5,728,067; 5,709,658; 5,685,312; 5,626,600; 5,620,417; 5,607,406; 5,554,118; 5,545,134; 5,531,690; 5,501,227; 5,496,600; 5,472,425; 5,468,225; 5,460,185; 5,458,613; 5,451,223; 5,443,457; 5,415,639; 5,413,559; 5,395,335; 5,383,853; 5,364,376; 5,350,395; 5,346,505; 5,336,184; 5,334,147; 5,328,472; 5,300,085; 5,380,283; 5,281,203; 5,263,963; 5,232,445; 5,195,978; 5,135,535; 5,061,273; 5,048,548; 4,762,129; 4,988,356; 4,947,864; 4,762,100; 4,748,982; US2003/0208221; US2003/012301; US 2002/0004053; and WO 99/13935.

BRIEF SUMMARY OF THE INVENTION

[0011] The present invention provides improved balloon and other interventional and diagnostic catheters which are adapted for facilitated exchange over guidewires. The catheters comprise both a catheter body and a separate guidewire tube, where the catheter body has at least a balloon inflation lumen and the guidewire tube has a guidewire lumen. The catheter body and the guidewire tube are not directly connected, and an axial gap will usually be present between a distal end of the catheter and a proximal end of the guidewire tube. Usually, the guidewire will pass between an open proximal end of the guidewire tube and an open distal end, although in some designs side slits or other holes may be formed in the guidewire tube for passage of an associated guidewire.

[0012] The guidewire tube will be disposed within a balloon or other interventional or diagnostic element which is secured directly to the catheter body. Usually, the balloon will act to indirectly connect the guidewire tube to the catheter body, but in other instances, different bridging or connection structure could be provided. In the preferred case where the interventional element is an angioplasty or stent delivery balloon, the catheter body is usually connected to the proximal end of the guidewire tube by a sleeve or neck portion of the balloon which bridges the gap between the catheter body and the guidewire tube. In such cases, the proximal end of the guidewire tube may be deflected so that it passes radially outwardly through a portion of the balloon.

[0013] The catheters and structures of the present, however, are not limited to balloon angioplasty or other balloon catheter devices. Other interventional and diagnostic elements which might find use with the present invention include mechanically expandable elements, such as malecotts and expandable blades; ultrasonic transducers, including both intervention and imaging transducers; radiation sources, including both isotopic and electronic radiation sources (e.g. X-ray sources); drug release mechanisms; atherectomy assemblies; thermal detectors, such as those used for detecting vulnerable plaque; optical coherence tomography (OCT) elements; and the like.

[0014] In a first preferred embodiment of the present invention, a balloon catheter comprises a catheter body having a proximal end, a distal end, and a balloon inflation lumen extending to the distal end, usually from the proximal end. A balloon having a distal end and a proximal end is attached to the distal end of the catheter body. The balloon has a expandable region between the distal and proximal ends thereof. A guidewire tube is

disposed within the balloon and has a proximal end and a distal end. The proximal end is spaced distally from the distal end of the catheter body and is not directly connected to the catheter body. In the specific embodiments, the guidewire tube is indirectly connected by a portion of the balloon which extends from the distal end of the catheter body and over the proximal portion of the guidewire tube.

[0015] Preferably, no portion of the catheter body will axially overlap with any portion of the guidewire tube. Usually, an axial gap of at least 1 mm will be maintained between the distal-most portion of the catheter body and the proximal-most portion of the guidewire tube, usually being at least 2 mm, often at least 3 mm, and sometimes 4 mm or more.

[0016] In the illustrated embodiments, the balloon has a distal neck portion, a proximal neck portion, and an expandable region therebetween. The proximal neck portion of the balloon may be joined over the distal end of the catheter body, may be joined under the distal end of the catheter body, or may be joined in a butt joint to the distal end of the catheter body.

[0017] In all these cases, the proximal end of the guidewire tube may open through either the neck portion of the balloon or the expandable region of the balloon. Usually, the proximal end of the guidewire tube will be deflected and sealed to a portion of the balloon. Alternatively, a hole may be formed in the side of the guidewire tube which is then connected directly or indirectly to the balloon to provide access into the guidewire lumen.

[0018] In further preferred constructions according to the present invention, the distal end of the guidewire tube will extend distally beyond the distal end of the balloon, typically by at least 1 mm, often by 5 mm, and sometimes by 10 mm or greater. Even more preferably, the distal end of the guidewire tube will be spaced distally from the distal end of the expandable region of the balloon by a distance which is greater than the distance of the proximal end of the guidewire tube and the proximal end of the expandable region of the balloon.

[0019] In all cases, the proximal end of the guidewire tube is usually positioned within the proximal neck or other portion of the balloon so that the inflation medium from the inflation lumen of the catheter can pass by the guidewire tube and enter the expandable of the balloon. For example, at least a proximal portion of the guidewire tube may have a diameter which is less than that of the proximal neck portion of the expandable balloon. Alternatively, the guidewire may terminate within the expandable region of the balloon, thus leaving the proximal neck portion empty and free to pass inflation medium.

[0020] In other specific designs, a reinforcement collar or sheath may be placed over the proximal neck portion of the expandable balloon, typically spanning the transition between the balloon and the distal end of the catheter body. Such collar or sheath can provide stress relief for the junction between the catheter body and the balloon. Alternatively, a distal end of the catheter body may be chamfered or cut at an angle so that the portion of the body which extends furthest in the distal directional may help support the junction with the balloon, where the proximal end of the guidewire tube is deflected in parallel to the angle of the distal end of the guidewire tube.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] Fig. 1 is a perspective view of a facilitated guidewire exchange catheter constructed in accordance with the principles of the present invention.

[0022] Fig. 2 is an enlarged view of a distal end of a first embodiment of the catheter of the present invention, shown in section.

[0023] Fig. 3 is an enlarged view of a second embodiment of a distal end of the catheter of the present invention, shown in section.

[0024] Fig. 4 is an enlarged view of a third embodiment of a distal end of the catheter of the present invention, shown in section.

[0025] Fig. 5 is a fourth enlarged view of a distal end of the catheter of the present invention, shown in section.

[0026] Fig. 6 is a fifth enlarged view of a distal end of the catheter of the present invention, shown in section.

DETAILED DESCRIPTION OF THE INVENTION

[0027] Catheters according to the present invention will comprise a catheter body having a proximal end and a distal end, and an interventional or diagnostic element disposed at or near the distal end of the catheter body. As described above, the element will most often be an expandable balloon of the type which is used for performing angioplasty and/or for delivering stents, grafts, or other vascular prosthesis. Such balloons are well described in the patent and medical literature. In other instances, however, the element of the present invention can be any one of or a combination of the interventional or diagnostic elements listed above. All these listed elements are exemplary, the catheter of the present invention may comprise at least most of the interventional and diagnostic elements of the type which are used or which

may be used in the future in interventional cardiology. Thus, the list provided above is intended to be exemplary, not exhaustive.

[0028] The catheter bodies of the present invention may also have a generally conventional structure. The catheter body will have a proximal end and a distal end with an expandable balloon or other interventional or diagnostic element mounted near the distal end. The dimensions, materials, and construction of the catheter body may vary widely and will depend on the particular application intended for the catheter. In the case of angioplasty and other intravascular coronary catheters, the catheter body will typically have a length in the range from 50 cm to 200 cm, usually in the range from 75 cm to 150 cm. The outside diameter of the catheter body will typically be in the range from 2f - 12f. The ability to utilize a separate guidewire tube which extends distally beyond from the catheter body and which is not co-extensive with the catheter body is particularly advantageous for small-diameter catheters, typically having a diameter in the range from 2 Fr to 6 Fr. over at least their distal ends.

[0029] The catheter bodies of the present invention will usually be formed from nylon and Pebax. Optionally, the catheter body or some portion thereof may be formed as a composite having a reinforcement material incorporated within a polymeric body in order to enhance strength, flexibility, and/or toughness. Suitable reinforcement layers include braiding, wire mesh layers, embedded axial wires, embedded helical or circumferential wires, and the like. As a further alternative, at least a proximal portion of the catheter body may in some instances be formed from super elastic other highly elastic hypotube materials. The catheter body will include at least one continuous lumen extending from at or near its proximal end to at or near its distal end in order to provide for balloon inflation. While additional lumen(s) may be provided, there will typically be no lumens within the catheter body itself intended for receiving a guidewire. That is, the guidewire will be received only through the guidewire lumen in the guidewire tube, as described in detail below.

[0030] In exemplary embodiment of a balloon catheter, the balloon is at or near the distal end of the catheter may be formed separately or integrally with the body itself. Usually, the balloon will be extruded and formed in a separate step and later joined to the distal end of the catheter body in a conventional manner, e.g. by adhesives, heat fusing, ultrasonic welding, or some combination thereof. In some cases, however, it will be possible to form the balloon integrally, i.e., as a single extrusion, together with the catheter body, where the dimensions of

the balloon may be imparted by heat expansion and setting in a non-matter. In either case, the interior of the balloon will be open to the continuous balloon inflation lumen of the catheter body. The guidewire tube will be present within the balloon but will be spaced distally from the distal end of the catheter body. In cases where the catheter body is formed separately from the balloon, the distal end of the catheter body will usually be the physical termination of the catheter body extrusion. In cases where the balloon is formed as a single extrusion with the catheter body (but later formed by heat expansion in setting) the distal end of the catheter body will be considered the point at which the balloon material is thinned and begins to flare relative to the proximal catheter body.

[0031] The catheter will also typically include a proximal hub located at or near the proximal end of the catheter body. The hub will serve in a conventional manner to provide a luer or other fitting in order to connect the catheter to a source of balloon inflation, such as conventional angioplasty activation device. Unlike most angioplasty balloon catheter hubs, however, the hub of the present invention need not have any port or other provision for sealingly receiving a guidewire. The guidewire tube is provided within the inflatable balloon or other interventional or diagnostic element of the catheter. The guidewire tube will have dimensions and will be composed of a material which is compatible with the remainder of the balloon catheter construction. In particular, the material will be bondable to the balloon material and will have sufficient flexibility, durability, pushability, and the like in order to provide for proper performance. The material of the guidewire tube will be selected to provide an appropriate guidewire lumen material to permit advancement of the catheter over a conventional guidewire. Optionally, the guidewire lumen of the guidewire tube may be coated with a lubricous material in order to reduce friction. The length, diameter, and lumen diameter of the guidewire tube will be selected to be compatible with the catheter dimensions overall. Typically, the guidewire tube will have a length in the range from 5 mm to 10 cm, typically from 5 mm to 7 cm. When utilized within an angioplasty or stent delivery balloon, the length of the guidewire tube will typically be 1 cm to 10 cm, and the outside diameter will typically be 2 Fr to 5 Fr.

[0032] Referring now to Fig. 1, an angioplasty balloon catheter 10 comprises a catheter body 12 having an inflatable balloon 14 at its distal end and a hub 16 at its proximal end. The hub includes a balloon inflation port 18, and a guidewire tube 20 is positioned within the balloon 14 and includes a proximal guidewire port 22 at its proximal end and a distal end guidewire port 24 at its distal end. The catheter 10 may thus be introduced over a

conventional guidewire GW by passing the distal guidewire port 24 over the proximal end PE and advancing the catheter until the proximal end PE emerges from the proximal guidewire port 22, as shown in Fig. 1. The catheter may then be advanced through a patient's vasculature over the guidewire in a generally conventional manner. The relatively short engagement length of the guidewire within the guidewire tube 20 facilitates exchange of the catheter for a subsequent catheter.

[0033] The guidewire tube 20 may be positioned within the inflatable balloon 14 in a number of different ways, as illustrated in Figs. 2-6. Fig. 2 illustrates guidewire generally as shown in Fig. 1. The balloon 14 is mounted over the distal end of catheter body 12 and secured by adhesives, heat bonding, ultrasonic bonding, or the like. In particular, the catheter body is secured within a proximal neck end 30 of the balloon which has an inner diameter generally corresponding to the outer diameter of the catheter body. Similarly, a distal neck portion 32 has an inner diameter generally corresponding to the outer diameter of the guidewire tube 20 and is attached thereto by adhesives, heat welding, ultrasonic welding, or the like. The proximal port 22 of the guidewire tube 20 is laterally deflected and terminates within a hole or passage in the proximal neck portion of the balloon 30. The guidewire tube 20 is not connected to the catheter body 12 in any way (other than indirectly by the proximal neck 30 of the balloon). That is, a gap G in the range from 0.1 mm to 2 cm may be left, typically being in the range from 1 mm to 5 mm. Similarly, the distal guidewire port 22 of the guidewire tube 20 will usually be closer to the expandable region 34 of the balloon 14 than is the proximal guidewire port 24. Usually, the proximal port 22 will be within a distance d_2 from the beginning of the expandable region 34 in the range from 0 mm to 1 cm, usually being from 0 mm to 5 mm. In contrast, the distal port 24 will be at a greater distance from the distal beginning of the expandable region 34, typically being at a distance d_1 in the range from 3 mm to 5 cm, typically from 5 mm to 3 cm, and often from 1 cm to 2 cm.

[0034] A first alternate construction for placement of the guidewire tube 120 within balloon 114 is illustrated in Fig. 3. In that instance, balloon 114 is received within the interior lumen of the catheter body 112 concealed thereto by adhesives, heat welding, ultrasonic welding, or the like. Proximal port 122 of the guidewire tube 120 is received within expandable region 134 of the balloon 114, rather than in the proximal neck portion 130 (as was the case in Fig. 2). Another difference is that distal guidewire port 124 terminates at the end of distal neck portion 132 of the balloon and does not extend therebeyond. Other aspects, however, may remain the same.

[0035] As a further alternative construction, a sleeve 240 will be received over the junction between balloon 214 and catheter body 212, as shown in Fig. 4. The sleeve 240 may be formed over the location where the catheter body 212 terminates to provide stress relief. Optionally, the sleeve 240 may extend further proximally, as shown in broken line, in order to provide additional stress relief and help anchor the balloon to the catheter body.

[0036] In an still further optional construction, the distal end of the catheter body 312 may be chamfered, i.e., cut at an angle, as shown at 350 in Fig. 5. Such geometry allows a leading or distal-most end of the catheter body 312 to be positioned opposite from the distal guidewire port 322 of guidewire tube 320. This construction leaves the desired gap between the guidewire tube and the catheter body, but provides additional support and column strength for the structure as a whole.

[0037] As illustrated in Fig. 6, in a further alternative construction for guidewire tube 420 has a straight geometry. Guidewire tube 420 has a diameter which is generally less than that of the catheter body 412. Thus, the proximal portion 421 of the guidewire tube lies within the proximal neck 430 of the balloon 414, leaving a substantial gap available for introduction of an inflation medium. In order to connect the tube to a proximal guidewire port 422, a short tube or other connector 460 is provided. Alternatively, the connection could be provided by using an adhesive or other connecting material between the neck 430 and the aperture in the guidewire tube 420. Note that the proximal end of the guidewire tube 420 will be blocked to prevent loss of inflation medium through the guidewire lumen therein.

[0038] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.